FORM PTO-1390
REV. 5-93

US DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEYS DOCKET NUMBER
P01,0338

U.S.APPLICATION NO. (if known, see 37 CFR 1.5)
09/937971

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/SE00/00573	**23 March 2000**	**31 March 1999**

TITLE OF INVENTION

A RATE ADAPTIVE PACEMAKER

APPLICANT(S) FOR DO/EO/US

MART MIN, ANDRES KINK and TOOMAS PARVE

pplicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay.
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.

5. ☒ A copy of International Application as filed (35 U.S.C. 371(c)(2)) - drawings attached.
   a. ☒ is transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ has been transmitted by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US)
6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2) -

7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. §371(c)(3))
   a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ have been transmitted by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☐ have not been made and will not be made.

8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).

9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).

10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern other document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 C.F.R. 1.97 and 1.98; **(PTO 1449, Prior Art, Search Report).**

12. ☒ An assignment document for recording. A separate cover sheet in compliance with 37 C.F.R. 3.28 and 3.31 is included. (Separate envelope)

13. ☐ A FIRST preliminary amendment.
    ☐ A SECOND or SUBSEQUENT preliminary amendment.

14. ☐ A substitute specification, including red-lined version

15. ☐ A change of power of attorney and/or address letter.

16. ☒ Other items or information:
    a. ☐ Request for Approval of Drawing Changes

    B ☒ Express Mail Label EL 843741752US

410 Rec'd PCT/PTO 0 1 OCT 2001

U.S.APPLICATION NO. (if known, see 37 C.F.R. 1.5)	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
09/937971	PCT/SE00/00573	P01,0338

17. ☒ The following fees are submitted:	CALCULATIONS	PTO USE ONLY
BASIC NATIONAL FEE (37 C.F.R. 1.492(a)(1)-(5): Search Report has been prepared by the EPO or JPO $890.00		
International preliminary examination fee paid to USPTO (37 C.F.R. 1.482) $710.00		
No international preliminary examination fee paid to USPTO (37 C.F.R. 1.482) but international search fee paid to USPTO (37 C.F.R. 1.445(a)(2) $740.00		
Neither international preliminary examination fee (37 C.F.R. 1.482) nor international search fee (37 C.F.R. 1.445(a)(2) paid to USPTO $1040.00		
International preliminary examination fee paid to USPTO (37 C.F.R. 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4) $100.00		
ENTER APPROPRIATE BASIC FEE AMOUNT =	$890.00	
Surcharge of $130.00 for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 C.F.R. 1.492(e)).	$	

Claims	Number Filed		Number Extra	Rate		
Total Claims	13	- 20 =	0	X $18.00	$	
Independent Claims	1	- 3 =	0	X $ 84.00	$	
Multiple Dependent Claims				$280.00 +	$280.00	
				TOTAL OF ABOVE CALCULATIONS =	$1170.00	
Reduction by ½ for filing by small entity, if applicable. Verified Small Entity statement must also be filed. (Note 37 C.F.R. 1.9, 1.27, 1.28)					$	
				SUBTOTAL =	$1170.00	
Processing fee of $130.00 for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(f)). +					$	
				TOTAL NATIONAL FEE =	1170.00	
Fee for recording the enclosed assignment (37 C.F.R. 1.21(h). The assignment must be accompanied by an appropriate cover sheet (37 C.F.R. 3.28, 3.31). $40.00 per property +						
				TOTAL FEES ENCLOSED =	$1170.00	
				Amount to be refunded	$	
				charged	$	

a. ☒ A check in the amount of $1170.00 to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. _____ in the amount of $ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. **501519**. A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 C.F.R. 1.494 or 1.495 has not been met, a petition to revive (37 C.F.R. 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

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A RATE ADAPTIVE PACEMAKER.

Technical field

The present invention relates to a rate adaptive pacemaker comprising a means for determining the demand of the patient's organism, a pacing rate controlling means for controlling the pacing rate in response to the patient's demands and a pacing rate limiting means for preventing the pacing rate from becoming too high.

Background Art

Too high pacing rates can appear in a rate adaptive pacemaker due to the physical demand of the patient's organism and heart. This may cause lack of oxygen supply to the myocardium. Thus, in certain conditions the heart may not be able to satisfy the physiological needs of the patient's organism and heart if the pacing rate is not limited.

Several different proposals for limiting the pacing rate upwards have been presented. Thus in e.g. US-A-5,350,409 a rate adaptive pacemaker is described having an upper pacing limit programmed beyond which rate the pacemaker will not generate and deliver stimulation pulses. US-A-5,792,195 discloses an acceleration sensed safe upper rate envelope for calculating the haemodynamic upper rate limit for a rate adaptive pacemaker. From the output signal from an accelerometer the time of occurrence of a specific heart sound in relation to a previously occurring ventricular depolarization event is then derived and this heart sound information is used to establish a haemodynamic upper rate limit for the pacemaker. Also EP-0 879 618 A1 describes a rate modulated heart stimulator having a programmable maximum sensor rate. This heart stimulator also includes an ischemia detector and in response to the detection of an ischemia the maximum allowable stimulation rate is decreased.

The limit values are determined from patients' diagnosis and the setting can be either constant or externally programable.

The purpose of the present invention is to propose a new way of continuously automatically limiting the pacing rate upwards according to the current ability of the patient's heart.

Disclosure of the Invention

This purpuse is obtained by a rate adaptive pacemaker according to claim 1.

Thus, in the pacemaker according to the invention the myocardium energy consumption and energy supply can be kept in balance, and since this relation, and not the heart rate, is of primary importance, the patient can feel more healthy and comfortable in various everyday life conditions, also in conditions of active work. According to the invention the pacing rate limiting means is adapted to limit the pacing rate upwards such that the energy consumed by the myocardium always is less than the energy supplied to the myocardium. In this way lack of oxygen supply to the myocardium is avoided.

According to the invention said pacing rate limiting means includes an upper limit setting means for setting an upper limit value for the pacing rate, and an upper limit determining means to determine the relation between energy supplied to the myocardium and energy consumed by the myocardium for calculating an upper pacing rate limit value from said relation for supply to said upper limit setting means. Thus, in this way the actual pacing rate is continuously compared to a set upper limit value and the actual pacing rate is limited to a maximum value equal to this limit value.

Preferred embodiments are set forth in the dependent claims.

According to such advantageous embodiments of the pacemaker according to the invention said pacing rate limiting means is adapted to limit the pacing rate such that the inequality

$$(t_{diast,rest}/t_{diast})\cdot(SV/SV_{rest}) < CR \quad (1)$$

is satisfied, alternatively said upper limit determining means is adapted to determine actual coronary resistance ratio (CRR) from the equation

$$\text{supplied energy} = \text{consumed energy} \quad (2)$$

and determine an upper pacing rate limit from the relation between actual coronary resistance ratio (CRR) and coronary reserve (CR), or said upper limit determining means is adapted to determine the upper pacing rate limit value from the equation

$$\text{upper pacing rate limit} = (60\cdot CR) \,/\, [t_{diast,rest}\cdot(SV/SV_{rest}) + CR\cdot t_{syst}] \quad (3)$$

where $t_{diastrest}$ denotes diastolic duration for the patient in rest conditions, t_{diast} actual diastolic duration for the patient, SV and SV_{rest} actual stroke volume and stroke volume for the patient in rest conditions respectively, and t_{syst} the actual systolic duration. The term "rest condition" is intended to cover not only resting by lying down but also other standard defined low load conditions such as sitting. A bioimpedance measurement unit is preferably provided to measure the intracardiac bioimpedance as a function of time and determine therefrom actual stroke volume SV and actual diastolic and systolic duration t_{diast} and t_{syst} respectively. Since the electrical bioimpedance can be effectively used to determine cardiac parameters, in particular the parameters mentioned above can be obtained from the time variation of the bioimpedance measured between the tip of an intracardiac electrode and the housing of a pacemaker when an exitation

current proceeds from the electrode tip, the parameters needed for preventing the pacing rate from becoming too high can be obtained in a very convenient manner by using a standard pacing lead.

Brief Description of the Drawings

The invention will now be described more in detail with reference to the enclosed drawings on which

fig. 1a shows the ventricular pressure-volume loop for a heart rate of 60 beats per minute,

fig. 1b shows the variation of arterial pressure as a function of time for the same heart rate,

fig. 2a and b show the corresponding pressure-volume loop and time variation curve for a twice as high heart rate of 120 beats per minute,

fig. 3 is a block diagram of an embodiment of the pacemaker according to the invention, and

fig. 4 illustrates the principle of bioimpedance measurement between the tip of an intracardiac electrode and the metal housing of the pacemaker.

Fig. 5 illustrates the relationships of the cardiac parameters of interest.

Description of Preferred Embodiments

As mentioned above, according to one embodiment of the pacemaker according to the invention an upper limit value for the pacing rate is determined based on a balance between the energy consumption of the myocardium and the energy supplied to the myocardium for high patient workloads.

Since the oxygen demand, or demanded energy consumption which is equal to the work of myocardium, is well correlated to the area S_{dem} within the ventricular pressure-volume loop shown in figure 1a, the following equations are valid

$$W = S_{dem} = \bar{\Delta}\,\bar{P} \times SV \qquad (4)$$

where W denotes the work of myocardium, $\bar{\Delta}\,\bar{P}$ the mean value of the ventricular pressure variations during a cardiac cycle, and SV the stroke volume.

Further, in figures 1 and 2, P_{as} denotes the atrial systolic pressure, P_{ves} the ventricular systolic pressure, P_{ved} the ventricular diastolic pressure and P_{ad} the atrial diastolic pressure.

The energy supplied to the myocardium can be derived from the time response curve of the arterial pressure shown in figure 1b. The area S_{supp} is namely proportional to the supplied energy E. Thus

$$E = S_{supp} \times K = (\bar{\Delta}\,\bar{P} \times t_{diast}) \times K \qquad (5)$$

where t_{diast} denotes the diastolic duration of the patient's heart and K a coefficient essentially representing the conductance for energy influx into the myocardium. The coefficient K can be expressed as

$$K = \frac{C_{O_2} \cdot k_{O_2}}{R} \qquad (6)$$

where C_{O2} denotes the difference of the blood oxygen concentration in the artery and vein, i.e. the oxygen uptake, k_{O2} the energy productivity of blood oxygen, and R the hydraulic resistance of the coronary arteries.

The energy balance W = E results in

$$\frac{SV}{t_{diast}} = K \qquad (7)$$

Thus, if

$$\frac{SV}{t_{diast}} > K \qquad (8)$$

the pacing rate must be reduced, because the myocardium does not get sufficient energy, though the patient's organism, i.e. body, can demand even an increase of the pacing rate.

From figures 1 and 2 it appears that the area S_{dem}, representing energy consumed by the myocardium, increases when the heart rate increases, whereas the area S_{SUPP} which is proportional to the energy supplied to the myocardium decreases with increasing heart rate. Thus it is obvious that for a certain heart rate energy balance can no longer be maintained.

The energy supplied to the myocardium can also be expressed as

$$E = V_{mc} \cdot AVD \cdot k_{O2} \qquad (9)$$

where V_{mc} denotes the blood volume flowing through the myocardium during one cardiac cycle and AVD the arteriovenous blood oxygen difference, i.e. equal to the blood oxygen uptake C_{O2}.

The blood volume flowing V_{mc} can be expressed as

$$V_{mc} = \int_0^{t_{diast}} f_c(t) \cdot dt \cdot = \bar{f}_c \cdot t_{diast} \qquad (10)$$

where $f_c(t)$ denotes the blood flow per time unit through the myocardium and $\bar{f}_c$ the mean value of this blood flow.

From equations (9) and (10) the following expression is obtained for the supplied energy E.

$$E = \bar{f}_c \cdot AVD \cdot k_{O2} \cdot t_{diast} \qquad (11)$$

since

$$f_c = \frac{\bar{P}}{R} \qquad (12)$$

the supplied energy E can be expressed as

$$E = \frac{\overline{P}}{R} \cdot (AVD \cdot k_{O_2} \cdot t_{diast}) \qquad (13)$$

and consequently the coronary resistance as

$$R = \frac{AVD \cdot k_{O_2} \cdot t_{diast}}{SV} \qquad (14)$$

in the case of energy balance, i.e. E = W.

A well known parameter expressing the work ability of the heart is the coronary reserve CR, which can be expressed as

$$CR = \frac{R_{rest}}{R_{min}} \qquad (15)$$

where R_{rest} denotes the resistance of the coronary arteries for the patient in rest conditions and R_{min} the minimum value of this resistance. Thus the coronary reserve CR expresses directly the ability of coronary arteries to widen during work, the resistance R then being reduced from R_{rest} to its minimum value R_{min}. The coronary reserve varies in a healthy heart from about 4 to 6,, but in the case of coronary artero-sclerosis it is lower, typically less than 2.

The current actual value of the ratio R_{rest}/R is called coronary resistance ratio CRR and equals

$$CRR = \frac{t_{diast,rest} \cdot AVD_{rest} \cdot k_{O_2} \cdot SV}{t_{diast} \cdot AVD \cdot k_{O_{2,rest}} \cdot SV_{rest}} \qquad (16)$$

Since $k_{O2,\ rest} = k_{O2}$ and by denoting

$$\frac{AVD_{rest}}{AVD} = q \qquad (17)$$

q can vary from 1.0 to 0.5, q is decreasing significantly below 1 only in case of anaerobic work of the myocardium.

Arteriovenous difference AVD of the oxygen concentration in blood, i.e. oxygen uptake, does not vary significantly with physical load up to the load allowable for the pacemaker patients, i.e. up to anaerobic load limit. This is so due to autonomous regulation of blood circulation inside the myocard.

Thus, the coronary resistance ratio CRR can be expressed as

$$CRR = \frac{t_{diast,rest}}{t_{diast}} \cdot \frac{SV}{SV_{rest}} \cdot q \qquad (18)$$

The coronary resistance ratio CRR expresses the degree of utilisation of the coronary reserve CR and when CRR = CR the complete coronary reserve is utilized, which means that the ability of the heart to maintain the energy balance E = W has reached near to its safe limit. If the coronary resistance ratio CRR becomes larger than the coronary reserve CR the pacing rate must be limited.

For q = 1 there is no risk for overpacing and for safe limitation of the pacing rate it is suitable to avoid anaerobic operation of the myocardium. Thus the following inequality can be used as criteria for pacing rate limitation.

$$\frac{t_{diast,rest}}{t_{diast}} \cdot \frac{SV}{SV_{rest}} < CR \qquad (19)$$

From the equation

$$\frac{t_{diast,rest}}{t_{diast}} \cdot \frac{SV}{SV_{rest}} = CR \qquad (20)$$

and the relation

$$T = t_{diast} + t_{syst} \qquad (21)$$

where T denotes the duration of the cardiac cycle in seconds, the following expression is obtained for the upper pacing rate limit in beats per minute

$$\text{upper pacing rate limit} = 60/T = (60 \cdot CR) \,/\, [t_{diast,rest} \cdot (SV/SV_{rest}) + CR \cdot t_{syst}] \qquad (22)$$

The parameters stroke volume SV, and the diastolic or systolic durations t_{diast} or t_{syst} are preferably determined from measured time variations of the electric intracardiac bioimpedance, cf. below, and the coronary reserve is obtained by standard physical stress test as using veloergometers or treadmills.

Figure 3 is a block diagram of an embodiment of the pacemaker according to the invention comprising a bioimpedance measurement unit 2 for measuring the time variation of the electric intracardiac bioimpedance $Z_c(t)$. This type of measurements is well known, see e.g. "Design of Cardiac Pacemakers", edited by John G. Webster, IEEE Press, 1995, pp. 380-386 and US-A-5,154,171, 5,280,429, 5,282,840 and 5,807,272. Thus the time variation of the intracardiac bioimpedance can be measured between the tip 4 of the intracardiac electrode 6 and the housing 8 of the pacemaker, when an excitation current is fed from the electrode tip 4, as schematically illustrated in figure 4. Thus a standard pacing lead can be used for this measurement.

From the measured time variations $\Delta Z_c(t)$ the parameters for calculating the upper pacing rate limit according to equation (22) above, or for checking the inequality (19), is determined in computing means 10, see figure 3.

The calculated upper limit value is supplied to an upper limit setting means 12 of a pacing rate limiter 14.

A pacing rate controller 16 is also provided for controlling the pacing rate of the pacer or pulse generator 18 in

response to the patient's demands. In a limiting unit 20 of the limiter 14 the demanded pacing rate is compared to the set upper limit pacing rate and the actual pacing rate is limited to the set upper limit value if the demanded pacing rate reaches this limit value. Thus in the pacemaker according to the invention an upper limit value for the pacing rate is continuously automatically determined and it is continuously automatically verified that the actual pacing rate does not exceed the present upper limit value. Alternatively, the pacemaker can be modified to continuously monitor that the inequality (19) above is satisfied.

Above bioimpedance measurements are described for determining necessary parameters like stroke volume SV, diastolic or systolic durations t_{diast} or t_{syst}. These parameters can, however, also be determined by other techniques. Thus these parameters can be determined from measured ECG's, by ultrasound technique, etc.

The relationships of the cardiac parameters of interest are illustrated in Fig. 5:

If load increases from Rest to some level (e.g. 100W), the stroke volume SV increases 1.2 to 1.5 times, and the diastole time $t_{diast} = t_{cycle} - t_{syst}$ decreases rapidly with the HR (e.g. 3x).

Falling of the coronary arterial hydraulic resistance due to widening of the blood vessels with the increase of myocardial work $W = S_{dem}$ compensates the decrease of the myocardial energy supply

$$E = S_{suppl} \cdot K\ (C_{O2};\ k_{O2};\ R).$$

The compenstion ability can be expressed by the coronary reserve CR = 2...5 for a typical patient.

Claims

1. A rate adaptive pacemaker comprising a means (2) for determining the demand of a patient's organism, a pacing rate controlling means (16) for controlling the pacing rate in response to the patient's demand, and a pacing rate limiting means (14) for preventing the pacing rate from becoming too high, said pacing rate limiting means (14) being adapted to limit the pacing rate upwards such that a predetermined relation is maintained between energy supplied to the myocardium and energy consumed by the myocardium, and including an upper limit setting means (12) for setting an upper limit value for the pacing rate, and an upper limit determining means (10) for determining the relation between energy supplied to the myocardium and energy consumed by the myocardium for calculating an upper pacing rate limit value from said relation for supply to said upper limit setting means (12), **characterized in** that said pacing rate limiting means (14) is adapted to limit the pacing rate upwards such that the energy consumed by the myocardium always is less than energy supplied to the myocardium.

2. The pacemaker according to claim 1, **characterized in** that said pacing rate limiting means is adapted to limit the pacing rate such that the inequality

$$(t_{diast,rest}/t_{diast})\cdot(SV/SV_{rest}) < CR$$

is satisfied, where $t_{diastrest}$ denotes diastolic duration for the patient in rest conditions, t_{diast} actual diastolic duration for the patient, SV and SV_{rest} actual stroke volume and stroke volume for the patient in rest conditions respectively, and CR the coronary reserve.

3. The pacemaker according to claim 1 or 2, **characterized in** that said upper limit determining means (10) includes an energy determining means for determining the energy supplied

to the myocardium and the energy consumed by the myocardium respectively, and a comparison means for comparing supplied energy and consumed energy for determining said relation.

4. The pacemaker according to claim 3, **characterized in** that said energy determining means is adapted to determine consumed energy as the product of mean value of ventricular pressure variations during a cardiac cycle and stroke volume.

5. The pacemaker according to claims 3 or 4, **characterized in** that said energy determining means is adapted to determine supplied energy from the time response curve of the arterial pressure during diastole.

6. The pacemaker according to claim 5, **characterized in** that said upper limit determining means (10) is adapted to determine actual coronary resistance ratio (CRR) from the equation

supplied energy = consumed energy

and determine an upper pacing rate limit value from the relation between actual coronary resistance ratio (CRR) and coronary reserve (CR).

7. The pacemaker according to any of the claims 1-6, **characterized in** that said upper limit determining means is adapted to determine the upper pacing rate limit value from the equation

$$\text{upper pacing rate limit} = (60 \cdot CR) / [t_{diast,rest} \cdot (SV/SV_{rest}) + CR \cdot t_{syst}]$$

where CR denotes the coronary reserve, $t_{diastrest}$ diastolic duration for the patient in rest conditions, SV and SV_{rest} actual stroke volume and stroke volume for the patient in rest conditions respectively, and t_{syst} the actual systolic duration.

8. The pacemaker according to any of the claims 2-7, **characterized in** that a bioimpedance measurement unit is

provided to measure the intracardiac bioimpedance as a function of time and determine therefrom actual stroke volume SV and actual diastolic or systolic durations t_{diast} or t_{syst} respectively.

9. The pacemaker according to any of the claims 2-7, **characterized in** that an ECG measuring and analyzing unit is provided to measure ECG and determine therefrom actual stroke volume SV and actual diastolic or systolic durations t_{diast} or t_{syst} respectively.

COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY (Includes Reference to PCT International Applications)	ATTORNEY'S DOCKET NUMBER P01,0558

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,
I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

"A RATE ADAPTIVE PACEMAKER"

the specification of which (check only one item below):

- ☐ is attached hereto
- ☐ was filed as United States application Serial No. __________
  on __________
  and was amended
  on __________ (if applicable).
- ■ was filed as PCT international application
  Number PCT/SE00/00573
  on March 23, 2000
  and was amended under PCT Article 19
  on __________ (if applicable).

I hereby state that I have reviewed and understand the content of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

PRIOR FOREIGN/PCT APPLICATION(S) AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. 119:

COUNTRY (if PCT indicate "PCT")	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 35 USC 119
Sweden	9901195-9	31.03.99	■ YES ☐ NO
			☐ YES ☐ NO
			☐ YES ☐ NO
			☐ YES ☐ NO
			☐ YES ☐ NO

Combined Declaration For Patent Application and Power of Attorney (Continued) (Includes Reference to PCT International Application)	ATTORNEY'S DOCKET NO. P01.0338

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:

PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S. FOR BENEFIT UNDER 35 U.S.C. 120:

U.S. APPLICATIONS		STATUS (Check one)		
U.S. APPLICATION NUMBER	U.S. FILING DATE	PATENTED	PENDING	ABANDONED

PCT APPLICATIONS DESIGNATING THE U.S.					
PCT APPLICATION NO	PCT FILING DATE	U.S. SERIAL NUMBERS ASSIGNED (if any)			

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected herewith.

And I hereby appoint all Attorneys identified by the United States Patent & Trademark Office Customer Number 26574, who are all members of the firm of Schiff, Hardin & Waite.

Send Correspondence to:	SCHIFF, HARDIN & WAITE Patent Department 6600 Floor Sears Tower, Chicago, Illinois 60606 Customer Number 26574	Direct Telephone Calls to: 312/258-5790

201	FULL NAME OF INVENTOR	FAMILY NAME MIN	FIRST GIVEN NAME MART	SECOND GIVEN NAME
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202	FULL NAME OF INVENTOR	FAMILY NAME KINK	FIRST GIVEN NAME ANDRES	SECOND GIVEN NAME
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203	FULL NAME OF INVENTOR	FAMILY NAME PARVE	FIRST GIVEN NAME TOOMAS	SECOND GIVEN NAME
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	POST OFFICE ADDRESS	POST OFFICE ADDRESS Rannala tee 3-7	CITY Tallinn	STATE & ZIP CODE/COUNTRY EE10917 Tallinn

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

SIGNATURE OF INVENTOR 201	SIGNATURE OF INVENTOR 202	SIGNATURE OF INVENTOR 203
DATE Sept. 26, 2001	DATE Sept. 26, 2001	DATE Sept. 26, 2001

United States Patent & Trademark Office

Office of Initial Patent Examination -- Scanning Division

Application deficiencies found during scanning:

☐ Page(s)_____ of _____ were not present for scanning. (Document title)

☐ Page(s)_____ of _____ were not present for scanning. (Document title)

☑ ***Scanned copy is best available.*** Declaration is too dark.